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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,954	11/30/2001	Harlan W. Waksal	IMCLON 3.0-003 CIPCONCONI	3116
77405	7590	08/26/2008	EXAMINER	
IMCLON			HOLLERAN, ANNE L	
Lerner, David, Littenberg, Krumholz & Mentlik, LLP				
600 South Avenue West			ART UNIT	
Westfield, NJ 07090			PAPER NUMBER	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/996,954	<b>Applicant(s)</b> WAKSAL, HARLAN W.	
	<b>Examiner</b> ANNE L. HOLLERAN	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 71-79,81-87 and 89-102 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 71-79,81-87 and 89-102 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/20/2007</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The amendment filed 5/5/2008 is acknowledged. Claim 80 was canceled. Claims 99-102 were added.

Claims 71-79, 81-87 and 89-102 are pending and examined on the merits.

#### ***Claim Rejections Withdrawn:***

The rejection of claims 71-87 and 89-98 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

The rejection of claim 80 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment canceling claim 80.

#### ***Claim Rejections Maintained:***

##### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 91 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that the specification fails to describe the genus of compounds that is encompassed by the functional term “immune system stimulator”.

Applicants failed to address this rejection. Therefore, the rejection is maintained for the reasons of record. The previous rejection is included below:

Claim 91 is drawn to a method comprising the treatment of patients with refractory tumors that have failed or been resistant to treatment with chemotherapy or radiation therapy comprising administering to a human without concomitant chemotherapy or radiation therapy, an epidermal growth factor receptor antagonist that is an anti-EGFR antibody or fragment thereof that retains the ability to bind to the EGFR, wherein administration is effective to inhibit growth of the refractory tumor, and further comprising administering an adjuvant that is an immune system stimulator.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is for purposes of the ‘written description’ inquiry, “*whatever is now claimed*” (see page 1117). The specification does not exemplify or provide any examples of immune system stimulators that would be effective in the claimed methods, or

Art Unit: 1643

provide any reasoning based on a structural analysis demonstrating a common structural feature for how to pick an “immune system stimulator” that would be effective in the claimed methods.

The skilled artisan cannot envision the detailed chemical structure of the encompassed “immune system stimulators” used in the method claims and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of manufacturing or testing the claimed process. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for making or testing it. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF’s were found unpatentable due to lack of written description for the broad class. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112, is severable from its enablement provision. (See page 1115).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 71-79, 81-87, 90, 92, 96, and 98-102 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Bos (Bos, M. et al., Proceedings of the American Society of Clinical Oncology, Abstract #1381, 1996) as evidenced by Herbst (Herbst, R.S. et al, Expert Opin. Biol.

Art Unit: 1643

Ther. (2001) 1(4): 719-732) for the reasons of record. This rejection applies to new claims 99-102.

Bos teaches that the antibody administered to the patients is C225. Bos teaches that 100mg/m<sup>2</sup> is a dose sufficient to achieve a serum concentration of 20 nM for greater than 7 days. Therefore, Bos teaches the limitations found in claims 99-102.

Applicant's arguments have been carefully considered but fail to persuade. The arguments presented in the amendment filed 5/5/2008 appear to be essentially the same arguments that have been presented previously and were not found persuasive (see previous Office action). The central argument applicant is asserting is that Bos, while teaching the treatment of advanced cancers, fails to teach treatment of refractory tumors, because Bos fails to use the term "refractory" in characterizing the patients. Applicant also discusses rejections based on the theory of inherency, and characterizes the examiner's arguments as based on the statement that "some" of the patients of Bos may have had cancer which was refractory to traditional treatments. This is a mischaracterization of the examiner's argument.

As an initial matter, the MPEP does not require that the Office provide proof that teachings of a reference are inherent, but instead requires the examiner to provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art (MPEP 2112). In the previous Office action, the examiner provide reasoning to support the contention that the patients in Bos were patients having refractory cancer, because the patients have advanced cancer, which is a cancer that is defined as often incurable, that Herbst teaches that at least one of the cancer types found in Bos, head and neck cancer, is known to be refractory to cancer treatments, and

Art Unit: 1643

further that for most of the cancers taught by Bos, there were established therapies known at the time of publication of Bos (therefore it is unlikely that these patients were treatment naïve patients with advanced cancer). Applicant has failed to rebut the reasoning used in the examiner's argument, and instead relies on stating there is a difference in the definitions of "refractory" and "advanced", stating that the Bos reference does not explicitly use the term "refractory", and then speculating on different reasons why it is possible that a group of patients with advanced cancer, but never before treated cancer (treatment naïve), might have possibly decided to enroll in a clinical trial instead of first attempting established therapies. Applicant's argument is not found persuasive because it fails to demonstrate that Bos' patients were in fact treatment-naïve patients, or even that it was more likely than not that they were treatment-naïve patients. Applicant then asserts that Herbst may not be used as a reference because its publication date is later than the effective filing date of the instant application. This is not found persuasive because Herbst is used as an evidentiary reference concerning the refractory nature of head and neck cancer to treatment. Therefore, its publication date need not be before the filing date of the instant application (see MPEP 2124). Therefore, the rejection is maintained for the reasons of record.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 71 and 89 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bos as evidenced by Herbst (*supra*) in view of Surani (US 5,545,807; issued Aug. 13, 1996) for the reasons of record.

Claims 71 and 93-95 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bos as evidenced by Herbst (*supra*) in view of Ladner (US 5,260,203; issued Nov. 9, 1993) for the reasons of record.

Claims 71 and 97 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bos (Bos, M. et al., Proceedings of the American Society of Clinical Oncology, Abstract #1381, 1996) in view of Malecka-Panas (Malecka-Panas, E. et al. Hepato-Gastroenterology, 44: 435-440, 1997) and Radinsky (Radinsky, R., European Journal of Cancer, 31A(7/8): 1091-1095, 1995) for the reasons of record.



*Response to Arguments:*

Applicant's arguments for the rejections under 35 USC 103(a) have been carefully considered, but fail to persuade. Applicant relies on the argument that Bos and Herbst do not teach refractory tumors, and the cited secondary references do not cure this deficiency. For the reasons stated above for the rejection under 35 USC 102(b), this argument is not found persuasive. Therefore, the rejections are maintained.

***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran  
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August 21, 2008  
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